MAY 2 8 2004

K041358

II SUMMARY AND CERTIFICATION
510(k) Summary as required by 807.92
Summary of Safety & Effectiveness Information

II. 1. Proprietary Device Name

VENOJECT® Luer Adapter

II.2. Classification Name

Blood Specimen Collection Device

II.3. Reason for Submission

New Device

II.4. Intended Use

The Terumo Venoject Luer Adapter is a sterile, non-invasive device that permits blood specimen collection from hypodermic needles, blood vessel catheters, or blood collection systems/devices with luer fittings. When blood samples are to be obtained with a single venipuncture, the luer adapter is a conduit between the collection needle and the collection container.

II.5. Description

The Terumo Venoject Luer Adapter is a sterile, single use device consisting of a cannula joined to a screw connector which is connected to a male luer taper. The cannula is covered with a synthetic isoprene rubber tip for stopping blood flow. When blood is collected using an evacuated blood collecting system, the collection container is placed over the cannula, pushing the rubber tip back, allowing blood flow. When the collection container is removed, the rubber tip extends back over the cannula, stopping blood flow. The luer adapter has no direct patient contact.

II.6. Substantial Equivalence

The "Venoject Luer Adapter", manufactured by Terumo Europe N.V., submitted in this 510(k) file is substantially equivalent in intended use, description/specifications, technology/principles of operation, materials and performance to the cleared "Venoject Luer Adapter", manufactured by Terumo Corporation which is the subject of K983490.

INTENDED USE:	Both devices being Luer Adapters for blood specimen collection, are sterile and for single use, permitting blood specimen collection from hypodermic needles, blood vessel catheters, or blood collection systems/devices with luer fittings. For blood samples obtained by single venipuncture, the luer adapter serves as a conduit between the needle and the collection container.

DESCRIPTION/ SPECIFICATIONS:	Both devices are made of a stainless steel cannula joined to a screw connector which is connected to a luer taper, and the cannula covered with a synthetic isoprene rubber tip. Materials used for proposed device and predicate are the same.
PRINCIPLE OF TECHNOLOGY STATEMENT:	The Venoject Luer Adapter made by Terumo Europe N.V. and the Venoject Luer Adapter made by Terumo Corporation are both operated manually.
PERFORMANCE:	The performance of the Venoject Luer Adapter has been evaluated and the device performs according to the specification. There are no significant differences in specifications and performance between proposed device and predicate.

II. 7. Additional Safety Information

The sterility of the Venoject Luer Adapter is assured by using a validated sterilization method qualified in accordance with EN 550: "Sterilization of Medical Devices: Validation and routine control of ethylene oxide" and ISO 11135: "Medical Devices: Validation and routine control of ethylene oxide sterilization" to a sterility assurance level (SAL) of 10^{-6} as required by EN 556-1: "Sterilization of Medical Devices - Requirements for medical devices to be designated "STERILE"Part - 1: Requirements for terminally sterilized medical devices".

Because this device does not come in direct contact with the patient, only biocompatibility screening tests have been performed. The results of these tests gave no indication that additional biocompatibility testing was necessary.

The expiration dating for the Venoject Luer Adapter has been established at 30 months.

II.8. Conclusion

The Venoject Luer Adapter manufactured by Terumo Europe N.V. and submitted in this 510(k) file is substantially equivalent in intended use, description, specifications, technology/principles of operation, materials and performance to the cleared Venoject Luer Adapter manufactured by Terumo Corporation which is the subject of K983490. Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

II.9. Preparation info

Date prepared:	05/2004
Prepared by:	Mrs. M.J. Aerts - Manager Regulatory Affairs
Prepared for:	TERUMO EUROPE N.V.
	Researchpark Zone 2, Interleuvenlaan 40, 3001 Leuven BELGIUM
Tel.:	0032 / 16 / 381 353

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 2 8 2004

Mrs. M.J. Aerts
Manager, Regulatory Affairs
Terumo Europe N.V.
RESEARCHPARK ZONE 2 HAASRODE
Interleuvenlaan 40
B-3001 LEUVEN-BELGIE (BEGLIUM)

Re: k041358
Trade/Device Name: Venoject® Luer Adapter
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA
Dated: May 19, 2004
Received: May 21, 2004

Dear Mrs. Aerts

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Use Indications for

510(k) Number (if known): K041358

Device Name: Venoject® Luer Adapter

Indications for Use:

The Terumo Venoject Luer Adapter is a sterile, non-invasive device that permits blood specimen collection from hypodermic needles, blood vessel catheters, or blood collection systems/devices with luer fittings. When blood samples are to be obtained with a single venipuncture, the luer adapter is a conduit between the collection needle and the collection container.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety